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**Adrenal (Excluding Mineralocorticoids)
7692****Morning Cortisol Levels In Patients With Established
Primary Adrenal Insufficiency**

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Background: Primary adrenal insufficiency (PAI) is rare: prevalence ~100-140/million and incidence 4:1 000 000/year in Western societies [1]. The diagnosis of PAI is suggested by an early-morning cortisol <140 nmol/L (5 µg/dL) [1]. The commonest cause in adults is autoimmunity (~90% in Western countries) and it is generally considered progressive once the diagnosis is made, although it has been reported that residual cortisol secretion is present in ~30% of patients². We have developed a modified-release formulation of hydrocortisone to replace the physiological cortisol circadian rhythm and are undertaking a Double-Blind, Double-Dummy, Two-Way Cross-Over,

Randomised, Phase II Study of Modified-Release Hydrocortisones: Chronocort[®] Versus Plenadren[®] in PAI. During recruitment, we were surprised by the number of patients who were ineligible as they had detectable morning cortisol levels. **Methods:** Main inclusion criteria: Participants with known PAI on stable glucocorticoid replacement therapy and an early morning pre-dose cortisol <50 nmol/L (1.8 µg/dl). Baseline serum cortisol was taken at ~0700h and measured in a central laboratory by ADVIA Centaur[®] immunoassay with the lower limit of detection <14nmol/l (<0.5 µg/dL). **Results:** 86 patients with PAI (autoimmune aetiology in 71), median age 52 years (range 20-73), 60 female, were screened in 8 centres in UK and Germany. 18 (21%) patients were excluded from the study based on morning cortisol >50 nmol/L (1.8 µg/dL), and of those 68 patients who qualified on the main inclusion criteria 51 (59% of screened) had a cortisol <14 nmol/L (<0.5 µg/dL). Of the 18 patients (autoimmune aetiology in 10) excluded based on their morning cortisol level, 9 (50%) were female and 11 (13% of screened), had morning cortisol ≥140 nmol/L (5.0 µ/dL). 12 patients with morning cortisol of >50nmol/L (1.8 µ/dL) were retested and only 2 then qualified; their initial morning cortisol levels were 70 and 51 nmol/L. In patients retested the median difference between retest and the initial sample was 13 nmol/L (range 1-421 nmol/L). **Conclusions:** In patients with an established diagnosis of PAI, the majority had undetectable morning cortisol, but cortisol was detectable in 41% of patients and above 140 nmol/L in 13% confirming previous publications². Retesting patients with a cortisol >50nmol/L showed very similar results suggesting that the detectable cortisol was not an artefact and likely due to background cortisol secretion. 1. Bornstein SR, et al. *J Clin Endocrinol Metab* 2016;101:364-89. 2. Pearce SHS, et al. *European Journal of Endocrinology* (2021) 184, R61–R67
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